REMARKS

As a preliminary matter, Applicants direct the Examiner's attention to the change in correspondence address pursuant to the paper filed herewith.

In the Office Action dated 26 August 2002, the Examiner has restricted the claims of the present application into six groups:

I. Claims 1-31, directed to antibodies against IL-1 and methods for making them;
II. Claims 32-59, directed to dual specific antibodies and methods for making them;
III. Claims 60-63, directed to a method for detecting IL-1;
IV. Claims 64-69, directed to a method for treatment with an antibody;
V. Claims 70-83, directed to a method for generating a recombinant antibody; and
VI. Claims 84-88, directed to nucleic acids encoding antibodies and means for expression.

Briefly, the reasons for restriction asserted in the Office Action are:

Groups I, II, and V	encompass distinct molecules and methods;
Groups I, II, III, IV, V, and VI	require different method steps, reagents, and have different goals and outcomes; and
Groups I, II, III, IV, and VI	encompass structurally and functionally distinct molecules that cannot be used together or interchangeably, and methods that require different method steps, reagents, and have different goals and outcomes.

The Examiner further requires election of species within group I, and requires election of one species if group I is elected (claims 1-4 and 12-31 have been identified as generic). Asserted species consist of: a) antibodies against SEQ ID NO:1; b) antibodies against SEQ ID NO:2; c) antibodies against SEQ ID NO:3; and d) antibodies against SEQ ID NO:4.

Applicants traverse the election requirement on the basis that the claims are drawn to a single inventive concept and a single inventive effort, the search and examination of which does not place a serious burden on the Examiner. The claims are but different aspects and embodiments of the same disclosed subject matter, varying in breadth or scope of definition.

Criteria for Restriction Between Patentably Distinct Inventions

In the Office Action (pages 2-5) the Examiner asserts that the present application contains patentably distinct inventions that require separate, noncoextensive searches. Applicants respectfully request reconsideration.

Proper restriction between independent and distinct inventions claimed in the same application requires (1) that the inventions must be independent and distinct as claimed, and (2) that there must be a serious burden placed on the Examiner by not requiring restriction. If either criterion is not met, restriction is not proper.

> If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.
>
> MPEP §803.

Current federal regulations and guidelines directed to patent applications provide for the examination in one application of product and method claims, even where distinct inventions exist, if the inventions are related. Such is the case here. The subject matter of Applicants' invention is directed to novel antibodies having dual specificity (i.e., "dual specific antibodies", capable of specifically binding at least two molecules). A dual specific antibody (including any antigen-binding portion thereof) that binds interleukin 1α (IL-1α) and interleukin 1β (IL-1β) is claimed as one specific embodiment of Applicants' invention (the claims of Group I). A method of making dual specific antibodies by exposing an antibody library or repertoire to an antigen that comprises a common structural feature of two structurally related molecules and selecting an antibody capable of specifically binding both structurally related molecules is claimed as one aspect of Applicants' invention (the claims of Group II). Nucleic acids encoding dual specific antibodies (the claims of Group VI), and methods for use for such novel dual specific antibodies (the claims of Groups III, IV, V) are also properly claimed under the present application.

Because the claims of the present invention are directed to novel dual specific antibodies, aspects of making such dual specific antibodies, and aspects of using such dual specific antibodies, Applicants respectfully submit that search and examination of this subject matter would not place a serious burden on the Examiner. In the absence of a serious burden, the Examiner MUST examine the application on the merits, irrespective of the presence of claims to independent and distinct inventions. Accordingly, withdrawal of the restriction requirement is respectfully requested.

Election of Species Within a Group

In the Office Action (page 5), the Examiner asserts election of a single disclosed species, i.e., an amino acid sequence, is required under 35 USC §121. Applicants' respectfully disagree.

Claims may be restricted to a single species only if the species are (i) "specifically different embodiments" of the claimed invention, and (ii) "mutually exclusive", and (iii) "patentably distinct" from each other. MPEP §806.04(e), (f), and (h). In addition, notwithstanding these criteria necessary for species restriction, 37 CFR § 1.146 permits that a "reasonable number" of species of an invention may be claimed in one application.

The present invention relates to a class of antibodies capable of binding at least two molecules, and the making and using thereof. Dual specific antibodies capable of binding IL-1α and IL-1β isolated by screening an antibody library or repertoire against an antigen that comprises a common structural feature of IL-1α and IL-1β selected from four peptides (SEQ ID NOs:1-4), provided in Applicants' specification are illustrative elements useful in Applicants' method for producing dual specific antibodies that fall within Applicants' novel class of antibodies. The recited antigenic elements are not independent inventive compounds possessing characteristics exclusive of other antigenic embodiments; they all exhibit a structural feature, which feature is common to IL-1α and IL-1β. If Applicants are forced to claim each individual embodiment as separate and distinct based solely upon amino acid sequence of the selected antigen, rather than the structural commonality possessed by the two structurally related molecules, this would cause each amino acid sequence permutation (identified by the Examiner as a separate species) to be a separately patentable embodiment, and Applicants would have no hope ever of obtaining full and proper patent coverage over the proper scope of their inventive method for producing dual specific antibodies. Applicants assert antigens that comprise a structural feature common to two structurally related molecules are not mutually exclusive species subject to restriction.

In addition, Applicants assert that, in combination with the recited structural commonality, the pending claims are, in fact, directed to a "reasonable number" of structural feature amino acid sequences; which number of sequences is four. For the foregoing reasons, withdrawal of this species restriction is believed to be proper and is respectfully solicited.

Conclusion and Provisional Election

Applicants submit, in view of the foregoing remarks, the claims currently under examination are seen to relate to a single inventive concept and derived from a single inventive effort, and that the claims are in a form and are of the sort that is properly viewed as relating to a single invention that should not be restricted under the provisions of 37 CFR §1.141 or §1.146. Applicants respectfully request that the restriction of Groups I-VI of the Office Action of 26 August 2002 be reconsidered and withdrawn.

Although Applicants believe that the restriction and the requirement of election are improper, and without in any way acquiescing to the reasons for the requirements set forth in the Office Action, but in order to be fully responsive to the Office Action, Applicants provisionally elect for examination the claims of Group I (i.e., claims 1-31). As to the election of a single species within Group I, Applicants elect antibodies against SEQ ID NO:3.

Respectfully submitted,

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